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REMARKS

Without acquiescing in any rejection, applicants propose to amend claims 37-44, 48, 52-54 and 57 in order to place the claims in condition for allowance, or at least reduce issues for appeal.

Applicants present a claim format that has similarities to that proposed by the examiner. Applicants propose to eliminate the phrase "SCR3-derived" from the claims. Applicants also propose to add a phrase that eliminates from coverage a mature SCR3, and thus would pertain to polypeptides comprising fragments thereof. Support for this amendment can be found throughout the application. See, for example, page 17, lines 31-35; page 19, lines 14-20; page 20, lines 31-35; and page 21, lines 20-24, as well as the title of the application.

Definiteness

On pages 3-4 of the Advisory action, the examiner made several indefiniteness rejections. Without acquiescing in the rejections, applicants have removed several of the terms considered indefinite by the examiner.

As stated before, for definiteness a claim need only reasonably apprise those skilled in the art of the utilization and scope of the invention. *Hybritech, Inc. v. Monoclonal Antibodies*, 231 USPQ 81, 94-95 (1986). Words are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the

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limitations of the English language. See MPEP §§ 707.07(g); 2111.01 (Rev. 1, February 2000). Claims are to be given their broadest reasonable interpretation consistent with applicants' specification. See MPEP § 2111 (Rev. 1, February 2000).. In sum, in order to reject the claims on definiteness grounds, it is incumbent on the examiner to show how and why the skilled person in the relevant art and possessing applicants' specification would not be apprised of the invention by the language-at-issue.

The examiner considers the phrase "chemically reactive amino acid residue" to be indefinite because all amino acids are potentially chemically reactive. From the standpoint of a physical chemist concerned with thermodynamics, the examiner's statement is true because any organic compound would be reactive with oxygen, for instance, in the case of fire or also reactive with strong inorganic acids and bases. The law, however, requires the claim to be looked at from the standpoint of a relevant audience, namely a protein chemist or molecular biologist, who would look at the known properties of amino acids under physiologic conditions. For example, page 4, line 21 of the specification mentions the amino acid cysteine, which is known to be reactive even when part of a peptide chain due to its sulphhydryl group. Other chemically reactive amino acids include glutamic acid and lysine. See page 4, lines 23-24 of the specification. Thus, the relevant skilled artisan would know what is meant by this phrase. To contend otherwise would impart on the skilled person a rigid absolutism that requires a departure from the sound judgment normally exercised by the skilled person as a matter of law. With regard to claim 42, these chemically reactive amino acids can

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be altered with known blocking or protecting agents. Applicants therefore request withdrawal of the rejection.

The examiner also considers "derivatizable," "derivatized" and "derivative" to be indefinite. Derivatizable and derivatized refer to with a compound that is capable of being derivatized or already has been derivatized, respectively. According to the specification, these terms refer to a chemical modification that serves as a "route for chemical linkage to other peptides or chemicals." See page 4, lines 23-25 of the specification. A derivative, of course, refers to the compound so derived. An exemplary derivative is S-(2-pyridyl) dithio. An exemplary lysine derivative is the 'MAP' peptide, which is a branched polymer of eight amino acids and is disclosed in the Posnett reference. See page 4, lines 28 to page 5, line 2 of the specification. In view of the teachings of the specification and common knowledge in the art (including the Posnett reference), applicants submit that the skilled protein chemist or molecular biologist would immediately recognize what is meant by these terms. Applicants therefore request withdrawal of the rejection.

Double Patenting and Prior Art

The examiner suggested on pages 2 and 4-5 of the Advisory Action that these rejection could be overcome by employing the "consisting of" transition phrase. Although applicants do not employ this phrase, applicants have amended the claims to make it clear that they cannot cover a mature SCR3. Applicants submit that this phrase

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thus distinguishes the subject matter of the rejections, and therefore the rejections should be withdrawn.

Request

Applicants submit that the claims are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,

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MARKED UP AMENDED CLAIMS

37. (Three times amended) **[A short consensus repeat-3 (SCR3)-derived]**
A polypeptide **[containing at least 6 and no more than]** **comprising a 6 to 23** amino
 acid **[residues and comprising a portion of Sequence (I) (] portion of SEQ ID NO:**
1[]:

CNPGSGGRKVFELVGEPsiYCTSNDDQVGiWSG (I)], wherein the
 polypeptide has at least one amino acid sequence selected from the group consisting of

(a) **[GGRKVF (] amino acids 6-11 OF SEQ ID NO: 1 [)],** and

(b) **[FELVGEPsiY (residues) amino acids 11-20 of SEQ ID NO: 1 [)],**

wherein the isolated polypeptide does not comprise a mature short consensus
repeat-3.

38. (Amended) The **[SCR3-derived]** polypeptide according to claim 37,
 further comprising a cysteine residue at the carboxyl terminus and the amino terminus of
 the polypeptide, thereby providing a capability to form a cyclic polypeptide via formation of
 a disulfide bond.

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39. (Twice amended) The **[SCR3-derived]** polypeptide according to claim 37, further comprising a chemically reactive amino acid residue located at **least one [or both of a]** position selected from the group consisting of the carboxyl terminus and the amino terminus of the polypeptide.

40. (Amended) The **[SCR3-derived]** polypeptide according to claim 39, wherein the chemically reactive amino acid residue is derivatized or derivatizable.

41. (Amended) The **[SCR3-derived]** polypeptide according to claim 40, wherein the terminal amino acid residue is cysteine derivatized with S- (2-pyridyl) dithio.

42. (Amended) The **[SCR3-derived]** polypeptide according to claim 37, wherein the polypeptide is altered **[at specific positions]** to remove chemically reactive amino acids.

43. (Three times amended) A multimeric polypeptide comprising at least two **[SCR3-derived]** polypeptide[s] **constituents** **[containing at least 6 and no more than 23 amino acid residues and comprising] that comprise a 6 to 23 amino acid** portion of **[Sequence (I) () SEQ ID NO: 1]**:
CNPGSGGRKVFELVGEPSIYCTSNDDQVGWSG (I)], wherein the polypeptide

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constituents [has] have at least one amino acid sequence selected from the group consisting of:

(a) [GGRKVF () amino acids 6-11 OF SEQ ID NO: 1 ()], and

(b) [FELVGPSIY (residues) amino acids 11-20 of SEQ ID NO: 1 ()],

wherein the polypeptide constituents do not comprise a mature short consensus repeat-3 and [, wherein] the polypeptide[s] constituents are linked to a core structure.

44. (Amended) The multimeric polypeptide according to claim 43, wherein the core structure [is a lysine derivative] comprises a derivative of lysine.

48. (Three times amended) A chimeric polypeptide comprising a host protein and [an SCR3-derived] an insert polypeptide [containing at least 6 and no more than 23 amino acid residues and] comprising a 6 to 23 amino acid portion of [Sequence (I) (I) SEQ ID NO: 1]: CNPGSGGRKVFELVGPSIYCTSNDDQVGIWSG (I)], wherein the polypeptide has at least one amino acid sequence selected from the group consisting of:

(a) [GGRKVF (residues) amino acids 6-11 of SEQ ID NO: 1(I)], and

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(b) [FELVGEPsiY (residues) amino acids 11-20 of SEQ ID NO: 1]], wherein the [SCR3-derived] insert polypeptide is inserted in a region of the host protein [that is not essential to the overall architecture or folding pathway of said host protein], and the insert polypeptide does not comprise a mature short consensus repeat-3.

52. (Three times amended) A process for preparing [an SCR3-derived] a polypeptide [containing at least 6 and no more than 23 amino acid residues and comprising a] comprising a 6 to 23 amino acid portion of [Sequence (I) () SEQ ID NO: 1]: CNPGSGGRKVFELVGEPsiYCTSNDDQVGWWSG (I)], wherein the polypeptide has at least one amino acid sequence selected from the group consisting of:

(a) [GGRKVF (residues) amino acids 6-11 of SEQ ID NO: 1]], and

(b) [FELVGEPsiY (RESIDUES) amino acids 11-20 of SEQ ID NO: 1]], and the polypeptide does not comprise a mature short consensus repeat-3, comprising the step of: condensing peptide units.

53. (Three times amended) A process for preparing [an SCR3-derived] a polypeptide [containing at least 6 and no more than 23 amino acid residues and comprising a] c mprising a 6 t 23 amin acid portion of [Sequenc (I) (I) SEQ ID

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NO: 1 [I]: **CNPGSGGRKVFELVGESPIYCTSNDDQVGIWSG (I)**, wherein the polypeptide has at least one amino acid sequence selected from the group consisting of:

(a) **[GGRKVF (residues) amino acids 6-11 of SEQ ID NO: 1(I)],** and

(b) **[FELVGESPIY (residues) amino acids 11-20 of SEQ ID NO: 1(I)],**

and the polypeptide does not comprise a mature short consensus repeat-3,

comprising the step of: expressing DNA encoding the **[SCR3-derived]** polypeptide in a recombinant host

cell, and recovering the **[SCR3-derived]** polypeptide.

54. (Three times amended) An isolated polynucleotide encoding **[an SCR3-derived] a** polypeptide **[containing at least 6 and no more than 23 amino acid residues wherein the SCR3-derived polypeptide comprises a] comprising a 6 to 23 amino acid** portion of **[Sequence (I) (SEQ ID NO: 1 (I))**:

CNPGSGGRKVFELVGESPIYCTSNDDQVGIWSG (I), wherein the **[SCR3-derived]** polypeptide has at least one amino acid sequence selected from the group consisting of:

(a) **[GGRKVF (residues) amino acids 6-11 of SEQ ID NO: 1(I)],** and

(b) **[FELVGESPIY (residues) amino acids 11-20 of SEQ ID NO: 1(I)],**

and the polypeptide does not comprise a mature short consensus repeat-3.

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57. (Three times amended) A pharmaceutical composition comprising

(1) a therapeutically effective amount of [an SCR3-derived] a polypeptide [containing at least 6 and no more than 23 amino acid residues and comprising a] comprising a 6 to 23 amino acid portion of [Sequence (I) (I) SEQ ID NO: 1 (I): CNPGSGGRKVFELVGEPsiYCTSNDDQVGWGS (I)], wherein the polypeptide has at least one amino acid sequence selected from the group consisting of:

(a) [GGRKVF (residues) amino acids 6-11 of SEQ ID NO: 1(I)], and

(b) [FELVGEPsiY (residues) amino acids 11-20 of SEQ ID NO: 1(I)] ,
and the polypeptide does not comprise a mature short consensus repeat-3, and

(2) a pharmaceutically acceptable carrier or excipient.